



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dr. Dianca Finch, 240-669-5503; dianca.finch@nih.gov. Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Products for treatment and prevention of Ebola Zaire disease

Description of Technology:

Scientists at the NIAID Vaccine Research Center have developed human monoclonal neutralizing antibodies for treatment and prevention of Ebola Zaire disease. The

monoclonal antibodies (mAbs) bind to different regions of the Ebola glycoprotein that are unique for these two mAbs. Alone or in combination, the mAbs prevent or reverse Ebola Zaire virus disease in non-human primates. Nonclinical studies have demonstrated complete protection against disease with a single antibody and complete protection against viremia by addition of a second antibody. The current nonclinical pharmacology demonstrates a favorable pharmacokinetic profile and there is a first-in-time human clinical trial projected for 2017. The anticipated indications for this technology include pre-and post-symptomatic treatment, and pre-and post-exposure prophylaxis.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR Part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Therapeutics
- Diagnostics

Competitive Advantages:

- Favorable pharmacokinetic profile
- Favorable manufacturing
- Complete protection against disease with a single unique mAb
- Complete protection with fewer administrations and/or lower doses than any other mAb
- Complete protection against viremia with two antibodies

Development Stage:

- In vivo data available (animal)
- Entering first-in-time human clinical trial (2017)

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Publications:

Corti D, et al., Protective monotherapy against lethal Ebola virus infection by a potentially neutralizing antibody. *Science*. 2016 Mar 18;351:1339-42. [PMID: 26917593]

Misasi J, et al., Structural and molecular basis for Ebola virus neutralization by protective human antibodies. *Science*. 2016 Mar 18;351:1343-6. [PMID: 26917592].

Intellectual Property:

HHS Reference No. E-045-2015—U.S. Provisional Application No. 62/087,087, filed December 3, 2014; PCT Application No. PCT/US2015/060733, filed November 13, 2015
HHS Reference No. E-278-2016- U.S. Provisional Application No.62,080,094, filed November 14, 2014; PCT Application No. PCT/IB2015/002342, filed November 13, 2015

Licensing Contact: Dr. Dianca Finch, 240-669-5503; dianca.finch@nih.gov.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize products for treatment and prevention of Ebola Zaire disease. For collaboration opportunities, please contact Dr. Dianca Finch, 240-669-5503; dianca.finch@nih.gov.

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Suzanne Frisbie.

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

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